NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ORTHO-MCNEIL PHARMACEUTICAL, INC. et al.,	
Plaintiffs,	
v.	Civ. No. 06-4999 (GEB)
LUPIN PHARMACEUTICAL, INC. et al.,	**MEMORANDUM OPINION**
Defendants.	

BROWN, Chief District Judge

This matter comes before the Court upon the following two motions:

(1) the motion for summary judgment of Defendants Lupin Pharmaceutical, Inc. and Lupin Ltd. (collectively "Lupin") [Docket # 59];

(2) the cross-motion for summary judgment of Plaintiffs Ortho-McNeil Pharmaceutical, Inc. ("OMP"), Ortho-McNeil, Inc. ("OMI"), and Daiichi Sankyo Co., Ltd. (Daiichi) (collectively "Plaintiffs"). [# 61]

Each party opposes its adversary's motion for summary judgment. [# 61, 64] The Court has considered the parties' submissions and decided these motions without oral argument pursuant to Federal Rule of Civil Procedure 78. For the reasons that follow, Plaintiffs' motion for summary judgment will be granted, and Lupin's motion for summary judgment will be denied.

I. BACKGROUND

On May 10, 1983, the United States Patent and Trademark Office ("PTO") issued U.S. Patent 4,382,892 (the "'892 Patent") to Plaintiff Daiichi. (Defs.' R. 56.1 ¶ 3. [#59]; Pl.'s R. 56.1 Resp. at 2. [#61]) The '892 Patent claims Ofloxacin, an antimicrobial agent. (Defs.' R. 56.1 ¶ 1. [#59]; Pl.'s R. 56.1 Resp. at 1. [#61]) On December 28, 1990, the United States Food and Drug Administration ("FDA") approved Ofloxacin tablets for commercial marketing in the United States, and the tablets were subsequently marketed under the trademark FLOXIN. (Defs.' R. 56.1 ¶ 4. [#59]; Pl.'s R. 56.1 Resp. at 4. [#61]) It is undisputed that the FDA-approved labeling and Orange Book entry for FLOXIN indicates the following: "Active Ingredient: Ofloxacin." (Pls.' R. 56.1 ¶ 1. [# 61]; Defs.' R. 56.1 Resp. ¶ 1. [# 66]) On December 30, 1991, the PTO granted Daiichi's application to extend the term of the '892 Patent pursuant to 35 U.S.C. § 156. (Defs.' R. 56.1 ¶ 5. [#59]; Pl.'s R. 56.1 Resp. at 5. [#61])

The Ofloxacin in FLOXIN contains two enantiomers. (Defs.' R. 56.1 ¶ 6. [#59]; Pl.'s R. 56.1 Resp. ¶ 6. [#61]) In chemistry, the term "enantiomers" denotes chemical components that are complete mirror images of each other. (Defs.' R. 56.1 ¶ 7. [#59]; Pl.'s R. 56.1 Resp. at 2. [#61]) Enantiomers are distinguished through their optical activity, or the direction in which the enantiomers rotate a plane of polarized light. (Pls.' R. 56.1 ¶ 3. [# 61]; Defs.' R. 56.1 Resp. ¶ 3. [# 66]) The combination of enantiomers in equal parts forms the racemate of the constituent enantiomers. (Defs.' R. 56.1 ¶ 10. [#59]; Pl.'s R. 56.1 Resp. at 10. [#61]) In previous litigation, Plaintiffs acknowledged that: (1) Levofloxacin is one of two biologically active enantiomers present in Ofloxacin; and (2) Levofloxacin and its corresponding enantiomer are present in Oflaxacin in a 1:1 ratio. (Defs.' R. 56.1 ¶ 12. [#59]; Pl.'s R. 56.1 Resp. at 2. [#61]) The parties dispute whether Ofloxacin is properly described as a racemic "mixture" (per Lupin), or a racemic

"compound" (per Plaintiffs). (Defs.' R. 56.1 ¶ 13. [#59]; Pl.'s R. 56.1 Resp. at 13. [#61]) It appears undisputed, however, that Ofloxacin is racemic as it is comprised of Levofloxacin and its corresponding enantiomer in equal amounts. (Pls.' R. 56.1 ¶ 2. [# 61]; Defs.' R. 56.1 Resp. ¶ 2. [# 66])

During the early 1980's, Daiichi scientists made a number of attempts to separate Ofloxacin into its constituent enantiomers, but were never able to do so. (Pls.' R. 56.1 ¶ 9, 10. [# 61]; Defs.' R. 56.1 Resp. ¶ 9, 10. [# 66]) In 1985, however, Daiichi scientists succeeded in synthesizing Levofloxacin using novel synthesis routes rather than obtaining it from racemic Ofloxacin. (Pls.' R. 56.1 ¶ 11. [# 61]; Defs.' R. 56.1 Resp. ¶ 11. [# 66]) Levofloxacin, the levorotatory enantiomer of Ofloxacin that the Daiichi scientists synthesized in 1985, is substantially optically pure, and is approximately twice as active as racemic Ofloxacin – the maximum possible difference in activity between an enantiomer and its racemate. (Pls.' R. 56.1 ¶ 12. [# 61]; Defs.' R. 56.1 Resp. ¶ 12. [# 66]) In addition, Levofloxacin is less toxic and ten times more water-soluble than Ofloxacin. (Pls.' R. 56.1 ¶ 13. [# 61]; Defs.' R. 56.1 Resp. ¶ 13. [# 66])

On June 20, 1986, Daaichi filed a patent application for Levofloxacin with the PTO. (Pls.' R. 56.1 ¶ 14. [# 61]; Defs.' R. 56.1 Resp. ¶ 14. [# 66]) The PTO initially rejected Daiichi's claims as obvious in view of Ofloxacin and the '892 Patent. (Pls.' R. 56.1 ¶ 14, 15. [# 61]; Defs.' R. 56.1 Resp. ¶ 14, 15. [# 66]) After considering the unexpected benefits of Levofloxacin over Ofloxacin, however, the Board of Patent Appeals and Interferences granted judgment to Daiichi, and U.S. Patent 5,053,407 (the "'407 Patent") was issued to Daiichi on October 1,

1991.[1] (Pls.' R. 56.1 ¶ 16, 17. [# 61]; Defs.' R. 56.1 Resp. ¶ 16, 17. [# 66]) Claim 2 of the '407 Patent is directed to a compound whose common name is Levofloxacin. (Pls.' R. 56.1 ¶ 18. [# 61]; Defs.' R. 56.1 Resp. ¶ 9, 10. [# 66]) Claim 5 of the '407 Patent is directed to a process for treating a patient with "an antimicrobially effective amount" of the same compound. (Pls.' R. 56.1 ¶ 19. [# 61]; Defs.' R. 56.1 Resp. ¶ 19. [# 66]) In prior litigation, Claims 2 and 5 of the '407 Patent were construed as referring to optically active and substantially optically pure Levofloxacin. (Pls.' R. 56.1 ¶ 20, 21. [# 61]; Defs.' R. 56.1 Resp. ¶ 20, 21. [# 66])

On December 20, 1996, the FDA granted marketing approval for injectable and tablet formulations of Levofloxacin as patented in the '407 Patent. (Defs.' R. 56.1 ¶ 16. [#59]; Pl.'s R. 56.1 Resp. ¶ 16. [#61]) The Levofloxacin patented in the '407 Patent has been subsequently marketed under the trademark LEVAQUIN. (Defs.' R. 56.1 ¶ 17. [#59]; Pl.'s R. 56.1 Resp. ¶ 17. [#61]) It is undisputed that the FDA-approved labeling and Orange Book entry for LEVAQUIN indicates the following: "Active Ingredient: Levofloxacin." (Pls.' R. 56.1 ¶ 24. [# 61]; Defs.' R. 56.1 Resp. ¶ 24. [# 66])

On February 18, 1997, Daiichi submitted to the PTO an application for extension of the term of the '407 Patent pursuant to 35 U.S.C. § 156. (Pls.' R. 56.1 ¶ 27. [# 61]; Defs.' R. 56.1 Resp. ¶ 27. [# 66]) Deciding whether a U.S. patent should be extended under the provisions of 35 U.S.C. § 156, and for how long, involves action on the part of both the PTO and the FDA. (Pls.' R. 56.1 ¶ 25. [# 61]; Defs.' R. 56.1 Resp. ¶ 25. [# 66]) A Memorandum of Understanding

[1] Plaintiff OMI asserts that it is an exclusive sub-licencee of the '407 Patent. (Defs.' R. 56.1 ¶ 23. [#59]; Pl.'s R. 56.1 Resp. ¶ 23. [#61]) Plaintiff OMP asserts that it is the holder of approved New Drug Application ("NDA") No. 020634 for several pharmaceutical formulations of Levofloxacin as patented in the '407 Patent. (Defs.' R. 56.1 ¶ 24. [#59]; Pl.'s R. 56.1 Resp. ¶ 24. [#61])

("MOU") between the PTO and the FDA sets forth the formal procedures each agency will follow when considering an application for patent term extension. (Pls.' R. 56.1 ¶ 26. [# 61]; Defs.' R. 56.1 Resp. ¶ 26. [# 66]) That MOU explains in pertinent part:

> [w]hile it is the responsibility of the Commissioner of Patents and Trademarks to decide whether an applicant has satisfied these six conditions [of 35 U.S.C. §§ 156(a)(1-5) and 156(d)(1)], the FDA possesses expertise and records regarding the last four and has certain direct responsibilities under 35 U.S.C. 156 for determining the length of the regulatory review period. Consequently, to facilitate eligibility decisions and permit the FDA and PTO to carry out their responsibilities under 35 U.S.C. 156, the FDA and PTO have entered into this agreement.

(Pls.' R. 56.1 ¶ 47. [# 61]; Defs.' R. 56.1 Resp. ¶ 47. [# 66]) The parties do not dispute that both the PTO and the FDA followed the MOU to the letter when deciding whether to extend the term of the '407 Patent. (Pls.' R. 56.1 ¶ 35. [# 61]; Defs.' R. 56.1 Resp. ¶ 35. [# 66])

As part of its application to extend the term of the '407 Patent, Daiichi specifically informed the PTO that FLOXIN had been previously approved by the FDA, and that the term of the '892 Patent covering racemic Ofloxacin had been previously extended. (Pls.' R. 56.1 ¶ 28. [# 61]; Defs.' R. 56.1 Resp. ¶ 28. [# 66]) Pursuant to the MOU, the PTO sent Daiichi's application for extension of the term of the '407 Patent to the FDA, and indicated that the '407 Patent, "would be eligible for extension of the patent term under 35 U.S.C. § 156 if the approval of LEVAQUIN is the first permitted marketing or use of the active ingredient thereof." (Pls.' R. 56.1 ¶ 29. [# 61]; Defs.' R. 56.1 Resp. ¶ 29. [# 66]) The PTO also informed the FDA that, "[Daiichi] has stated that the 'corresponding racemate Floxin' has been previously approved." (Pls.' R. 56.1 ¶ 30. [# 61]; Defs.' R. 56.1 Resp. ¶ 30. [# 66]) On July 18, 1997, the FDA sent a letter to the PTO stating in pertinent part:

> A review of the Food and Drug Adminsitration's official records indicates that this product [LEVAQUIN] was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp 1224 (E.D. Va. 1989), aff'd 894 F.2d 392 (Fed. Cir. 1990).

(Pls.' R. 56.1 ¶ 31. [# 61]; Defs.' R. 56.1 Resp. ¶ 31. [# 66]) On August 4, 1999, following additional correspondence between the PTO and the FDA that established the length of the FDA's regulatory review of LEVAQUIN and the corresponding length of the term extension, the PTO extended the term of the '407 Patent. (Pls.' R. 56.1 ¶ 32. [# 61]; Defs.' R. 56.1 Resp. ¶ 32. [# 66]) The term extension granted by the PTO was 810 days, which moved the expiration of the '407 Patent from October 1, 2008, to December 20, 2010. (Defs.' R. 56.1 ¶ 19. [#59]; Pl.'s R. 56.1 Resp. ¶ 19. [#61])

The parties to this case do not dispute that the PTO's decision to extend the term of the '407 Patent is consistent with the PTO's prior decisions in similar situations. Indeed, following the practice and procedure set out in the MOU, the PTO, informed by the expertise of the FDA, has considered at least five other applications for patent term extensions for patents covering enantiomeric products subsequent to approval of their corresponding racemates. (Pls.' R. 56.1 ¶ 48. [# 61]; Defs.' R. 56.1 Resp. ¶ 48. [# 66]) In each such case, the PTO and the FDA, acting in concert pursuant to the MOU, have determined that the patent covering the enantiomeric product was entitled to extension, and the PTO has granted the patent term extension pursuant to 35 U.S.C. § 156. (Pls.' R. 56.1 ¶ 49. [# 61]; Defs.' R. 56.1 Resp. ¶ 49. [# 66])

At issue in this case is the foregoing decision of the PTO to grant Daiichi an extension of the '407 Patent pursuant to 35 U.S.C. § 156(a). On July 14, 2006, Lupin submitted ANDA No.

78-424 to the FDA seeking approval of Levofloxacin tablet formulations. (Defs.' R. 56.1 ¶ 26. [#59]; Pl.'s R. 56.1 Resp. ¶ 26. [#61]) Subsequently, on September 29, 2006, Lupin notified Plaintiffs by letter that it had submitted ANDA No. 78-424. (Defs.' R. 56.1 ¶ 27. [#59]; Pl.'s R. 56.1 Resp. ¶ 27. [#61]) In that letter, Lupin also informed Plaintiffs that in ANDA No. 78-424, Lupin had certified that in its opinion and to the best of its knowledge, Lupin's tablet formation would not infringe on the '407 Patent when marketed after October 1, 2008 – the date the '407 Patent was originally scheduled to expire before it was extended by the PTO. (Defs.' R. 56.1 ¶¶ 27, 28. [#59]; Pl.'s R. 56.1 Resp. ¶¶ 27, 28. [#61])

On October 17, 2006, in response to Lupin's actions, Plaintiffs filed the complaint in this case. (Compl.) [#1] The complaint contains the following: (1) Plaintiffs' allegation of infringement of the '407 Patent by Lupin; (2) Plaintiffs' request for a declaratory judgment of validity regarding the term extension for the '407 Patent. (*Id.*) The parties subsequently narrowed the issues for decision. On June 11, 2007, the Court entered a consent order in which the parties stipulated the following in pertinent part: (1) the '407 Patent was validly issued by the PTO; (2) the '407 Patent is enforceable by Plaintiffs; (3) the Levofloxacin tablets Lupin intends to market pursuant to ANDA No. 78-424 will contain the compound claimed in Claim 2 of the '407 Patent; (4) the Levofloxacin tablets Lupin intends to market pursuant to ANDA No. 78-424 will contain an antimicrobially effective amount of the compound claimed in Claim 5 of the '407 Patent; (5) Lupin will not contest at trial or otherwise the validity and enforceability of the '407 Patent, or the infringement of Claims 2 and 5 of the '407 Patent by the Lupin Levofloxacin Products; (6) that if this Court holds the PTO's extension of the '407 Patent is valid, Lupin will not contest that its filing of ANDA No. 78-424 is an act of infringement on Claim 2 of the '407

Patent pursuant to 35 U.S.C. § 271(a); and (7) that if this Court holds the PTO's extension of the '407 Patent is valid, Lupin will not contest that the sale of the Lupin Levofloxacin Products contemplated in ANDA No. 78-424, as labeled and if used in accordance with that labeling, will constitute infringement of Claim 5 of the '407 Patent pursuant to 35 U.S.C. § 271(b). (GEB Order 6/11/07) [# 28]

In the parties' present cross-motions for summary judgment, therefore, the sole issue before the Court is whether the PTO's extension of the term of the '407 Patent is valid. If it is, Plaintiffs seek a declaratory judgment to that effect. Conversely, if the term extension is invalid, Lupin seeks a declaratory judgment to that effect, and reinstatement of the original expiration date for the '407 Patent – October 1, 2008. For the reasons that follow, the Court will grant Plaintiffs' cross-motion for summary judgment, and declare valid the PTO's extension of the term of the '407 Patent.

II. DISCUSSION

A. Legal Standard

A party seeking summary judgment must "show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c); see also *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Hersh v. Allen Prod. Co.*, 789 F.2d 230, 232 (3d Cir. 1986). The threshold inquiry is whether there are "any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986) (noting that no issue for trial exists unless there is sufficient evidence favoring the nonmoving party for a jury to return a verdict in its favor). In deciding whether triable issues of fact exist,

the court must view the underlying facts and draw all reasonable inferences in favor of the non-moving party. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587, (1986); *Pa. Coal Ass'n v. Babbitt*, 63 F.3d 231, 236 (3d Cir. 1995).

B. Application

The present cross-motions present the single issue of whether the PTO's decision to extend the term of the '407 Patent was valid. All parties agree that the extension of the terms of U.S. patents is governed by 35 U.S.C. § 156, a provision of the Hatch-Waxman Act of 1984, which establishes in pertinent part:

> **35 U.S.C. § 156 Extension of patent term**
>
> **(a)** The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b), if –
> . . . .
>
> **(5)(A)** except as provided in subparagraph (B) or (C), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred;
> . . . .
>
> **(f)** For purposes of this section:
>
> **(1)** The term "product" means:
> **(A)** A drug product
> . . . .
>
> **(2)** The term "drug product" means the active ingredient of –
> **(A)** a new drug, antibiotic drug, or human biological product . . . including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

The United States Court of Appeals for the Federal Circuit has established that, "[t]he

Director of the PTO is charged with deciding whether [a] patent is entitled to term extension, a decision which is given 'great deference.'" *Pfizer, Inc. v. Ranbaxy Labs Ltd.*, 457 F.3d 1284, 1290 (Fed. Cir. 2006) (quoting *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 399 (Fed. Cir. 1990)). A party seeking to invalidate the PTO's decision to extend the term of a patent must establish by clear and convincing evidence that the term extension was invalid. *Id.* at 1291. The Supreme Court has established that evidence is clear and convincing if it, "could place in the ultimate factfinder an abiding conviction that the truth of its factual contentions are 'highly probable.'" *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984) (internal citations omitted). Further, the Federal Circuit has established that when drafting 35 U.S.C. § 156, Congress left to the PTO's technical expertise the determination of whether a patented chemical compound named in a patent term extension application falls within the statutory definition of the term "product." *Quigg*, 894 F.2d at 399. Accordingly, courts, "give great deference to the [PTO's] determination as to which patented compounds fall within Congress' definition of 'products.'" *Id.*

Applying this standard here, the single issue presented by these summary judgment motions is straightforward: is Lupin able to present at trial clear and convincing evidence that the PTO's decision to grant a patent term extension to an enantiomer (Levofloxacin) whose racemate (Ofloxacin) has previously been granted a patent term extension runs afoul of 35 U.S.C. § 156? Certain basic undisputed facts paired with clear controlling precedent militates the Court's conclusion that Lupin can not do so, and that the PTO's decision to extend the '407 Patent term is therefore valid as a matter of law.

In support of the present summary judgment motion Lupin argues, in sum, that the

PTO's extension of the term of the '407 Patent is invalid because the PTO, acting in concert with the FDA, has improperly determined that Levofloxacin is a "product" under 35 U.S.C. § 156. (Defs.' Mot. Br. at 12-18.) [# 59] Lupin argues that because Levofloxacin is present in racemic Ofloxacin as an enantiomer, the PTO and FDA's determination that Levofloxacin is a "product" runs afoul of 35 U.S.C. § 156. (*Id.*) In a broader sense, given the undisputedly consistent determination of the PTO and FDA that enantiomers are "products" within the meaning of 35 U.S.C. § 156, Lupin appears to argue that the PTO has uniformly misapplied that statute. Plaintiffs assert that Lupin's foregoing argument fails under well established Federal Circuit precedent, and that Lupin cannot possibly meet its burden of proof in this case. (Pls.' Mot. Br. at 21.) [# 61] The Court concludes Plaintiffs are correct.

In this case, the parties do not dispute that the PTO's decision to extend the term of the '407 Patent is consistent with the PTO's prior decisions in similar situations. Indeed, following the practice and procedure set out in the MOU, the PTO, informed by the expertise of the FDA, has considered at least five other applications for patent term extensions for patents covering enantiomeric products subsequent to approval of their corresponding racemates. (Pls.' R. 56.1 ¶ 48. [# 61]; Defs.' R. 56.1 Resp. ¶ 48. [# 66]) In each such case, the PTO and the FDA, acting in concert pursuant to the MOU, have determined that the patent covering the enantiomeric product was entitled to extension, and have granted the patent term extension pursuant to 35 U.S.C. § 156. (Pls.' R. 56.1 ¶ 48. [# 61]; Defs.' R. 56.1 Resp. ¶ 48. [# 66]) Thus, the undisputed facts clearly establish the PTO has determined that enantiomers are "products" eligible for patent term extensions pursuant to 35 U.S.C. § 156, regardless of whether the patent term of the enantiomer's racemate has also been extended. The Federal Circuit's decision in

Quigg establishes that this Court must give great deference to this determination by the PTO. *Quigg*, 894 F.2d at 399. Having reviewed all of the parties' submissions, the Court concludes that Lupin is not able to present clear and convincing evidence that the PTO's decision to extend the term of the '407 Patent is invalid. Because the undisputed evidence reveals that Lupin cannot meet its burden, its motion for summary judgment will be denied, and Plaintiffs' motion for summary judgment will be granted.

III. CONCLUSION

For the foregoing reasons, Lupin's motion for summary judgment will be DENIED, and Plaintiffs' motion for summary judgment will be GRANTED. [#59, 61] As such, the Court will declare the PTO's extension of the term of the '407 Patent valid. The Court will instruct the Clerk of the Court to close this case. An appropriate form of order accompanies this memorandum opinion.

Dated: April 30, 2009

/s/ Garrett E. Brown, Jr.
GARRETT E. BROWN, JR., U.S.D.J.